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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ROBERT C. KAIN, JR.
750 SOUTHEAST THIRD AVENUE
SUITE 100
FT LAUDERDALE, FL 333161153

EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/757,680

Applicant(s)

MORRIS ET AL.

Examiner

Kathleen Sonnett

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2007 has been entered.

Response to Arguments

2. Applicant's arguments filed 1/24/2007 have been fully considered but they are not persuasive.

3. Applicant has indicated several passages contained in the instant specification that indicate that the proximal actuator is transversely or laterally attached and not longitudinally attached to the medical device. The examiner agrees that the actuator can be attached laterally to the medical device. The examiner also agrees that the actuator is disclosed as being laterally attached to and not longitudinally attached to a medical device (i.e. actuation sleeve). However, the wording of the claims 10, 17, and 18 includes the limitation "not longitudinally attachable". The limitation "not longitudinally *attachable*" is different than "not longitudinally *attached*". "Not longitudinally attachable" covers the fact that the actuator cannot be longitudinally attached to a medical device. However, there is no structure on the proximal actuator that would prohibit longitudinal attachment of an elongated actuation sleeve and wire. That is, the retaining devices can be opened and a user can either place the sleeve within the open retaining devices laterally or by longitudinally sliding the sleeve into the open retaining devices. Although the actuator of the instant application is laterally and not longitudinally attached to a medical device, it does not

Art Unit: 3731

mean that it is not longitudinally *attachable*, rather that it is not longitudinally *attached*.

Therefore, the 35 U.S.C. 112 1st paragraph rejection has been maintained.

4. Applicant also amended claims 1 and 16 to include that the medical device is coupled to the actuation sleeve. However, the medical device and actuation sleeve are still not positively recited. The fact that the medical device appears in the body of the claim does not mean that it is positively recited, only that the element from the preamble is being referred to. It is still only functional language; movement of the retaining devices operates a medical device that is coupled to an actuation sleeve. The actuator must only be capable of operating a medical device that is coupled to an actuation sleeve through movement of two retaining devices. The claims are drawn toward an actuator that can be used in combination with a medical device. If applicant wants to claim the combination, the claim needs to be drawn to a device that includes an actuator, actuation sleeve, and medical device as well as including that, for example, the first retaining device is removably attached to the first section instead of being removably attachable.

5. The amendments to claims 1, 16, 18, and 39, have overcome the 35 U.S.C. 112 1st paragraph rejections regarding the movability of the retaining devices.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10 and 17-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

Art Unit: 3731

claimed invention. Although the instant specification includes that the actuator is laterally and not longitudinally attached (mounted) to the actuation sleeve/medical device, the limitation "not longitudinally *attachable*" is different than "not longitudinally *attached*". "Not longitudinally *attachable*" covers the fact that the actuator cannot be longitudinally attached to a medical device. However, there is no structure on the proximal actuator that would prohibit longitudinal attachment of the elongated actuation sleeve and wire. That is, the retaining devices can be opened and a user can either place the sleeve within the open retaining devices laterally or by longitudinally sliding the sleeve into the open retaining devices. Although the actuator of the instant application is laterally and not longitudinally attached to a medical device, it does not mean that it is not longitudinally *attachable*, rather that it is not longitudinally *attached*. No embodiment is presented with structure that would prohibit an actuation sleeve from being longitudinally attached to the retaining devices.

Claim Objections

8. Claim 9 is objected to because of the following informalities: typographical error. There appears to be some missing text in line 2 of claim 9, immediately following the phrase "at least two". Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **Claims 1, 7-9, 11-16, 39, and 45-52** are rejected under 35 U.S.C. 102(b) as being anticipated by Darrey (U.S. 3,609,638). Regarding claims 1, 16, and 39, Darrey discloses a

Art Unit: 3731

proximal actuator for a medical device that comprises an actuator body (6) having a first retaining device and a movably mounted second retaining device such that longitudinal movement of an actuation sleeve relative to a wire can be caused by special movement between the first and second retaining devices. The retaining devices are laterally openable clips that are attachable to an actuation sleeve.

11. Regarding claims 7 and 45, the first retaining device is in a fixed position relative to the actuator body when the wings (10, 11) of the first spring clip are in an apart position. That is, the retaining devices are held in place unless they are opened, which allows them to slide along the body of the actuator.

12. Regarding claim 8 and 46, the second retaining device is longitudinally movable from the first position to a second position relative to the first retaining device when the wings are brought toward each other.

13. Regarding claims 11-14 and 49-52, the first and second retaining devices are spring loaded clips that have alignment indicators. For example, the indicators could be considered the curved sides of the clip. When a tube rests against the curve, it is properly aligned. Without any structure, the alignment indicators could be considered any part of the clip that can serve as a reference point.

14. Regarding claims 47 and 48, the actuator of Darrey is capable of attaching to the device described in the preamble such that movement of the retaining devices would result in an expandable frame being opened and closed.

15. Regarding claims 9, 15, 47, and 48, the actuator of Darrey meets all of the structure limitations positively recited the claims from which they depend. Furthermore, Darrey is capable of opening and closing an expandable frame by virtue of the relative lateral movement of the first and second retaining devices.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. **Claims 1-9, 11-16, and 32-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Forrer (U.S. 4,576,529) in view of Darrey (U.S. 3,609,638). Forrer discloses an actuator body (1) having a first retaining device (clamp on 1) and a movably mounted second retaining device (clamp on 1a) that are attachable to an actuation sleeve. If an actuation sleeve and wire are attached, longitudinal movement of an actuator sleeve relative to a wire can be caused by relative movement between the first and second retaining devices. The first and second retaining devices are attachable to the actuation sleeve and the second retaining device is moveable relative to the first retaining device (col. 1 ll. 34-41). Forrer fails to disclose that the first and second retaining devices are laterally openable clips.

18. However, Darrey discloses that laterally openable clips are well known for use in clamping assemblies. These laterally openable clips are spring clips. Such clips are advantageous because they can be quickly adjusted without the use of special tools and at the same time have a tight hold on the object that is being clamped (col. 3 ll. 1-3). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Forrer to include laterally openable spring clips as made obvious by Darrey instead of the arm portions that are sprung closed in a clamping fashion by a clamping screw because the laterally openable spring clips can be quickly adjusted without the use of a clamping screw.

19. Regarding claim 32, Forrer discloses a deployment handle removably attachable to an expandable device, the deployment handle comprising, a body with a handle grip portion (20) including a sleeve (6), a first retaining device (clip on 1) affixed to the sleeve and removably attachable to an actuation sleeve, a sliding member (14) with a first end positionable through the aperture of the sleeve, a second retaining device (clip on 1') affixed to the second end of the sliding member and removably laterally attachable to an actuation sleeve, and a control actuator (col. 2 lines 57-60) movably engaging the first end of the sliding member within the aperture such that the control actuator moves the second retaining member from a first position to a second position relative to the first retaining device (col. 1 lines 34-41).

20. Regarding claims 2 and 40, Forrer discloses a grip portion (20) having a sleeve (6) defining an aperture, wherein the first retaining device is affixed to the sleeve (Fig. 3).

21. Regarding claims 3 and 41, Forrer discloses a sliding member (14) that has a first end that is positionable through the aperture of the sleeve.

22. Regarding claims 4 and 42, the second retaining device is affixed to the second end of the sliding member (col. 1 lines 37-41).

23. Regarding claims 5, 6, 43, and 44, the first end of the sliding member (14) is threaded and the proximal actuator further comprises a control actuator (col. 2 lines 51-59 and col. 1 lines 37-41) moveably engaging the threaded first end of the sliding member within the aperture, such that the control actuator moves the second retaining member from a first to a second position relative to the first retaining member.

24. Regarding claims 7 and 45, the first retaining device is in a fixed position (col. 1 lines 37-41). Forrer discloses that one or both of the jaw members are movable backward and forward as either one or both of the jaw members are threaded to engage with the rotatable spindle.

Art Unit: 3731

25. Regarding claims 8, 9, and 46, the second retaining device is longitudinally movable from a first position to a second position relative to the first retaining member.

26. Regarding claims 15, 33, 34, 47, and 48, the device disclosed by Forrer meets all of the structural limitations positively recited in claims from which claims 15, 33, 34, 47, and 48 depend. An actuation sleeve and a wire can be retained in the retaining members. Furthermore, Forrer is capable of opening and closing an expandable frame by virtue of the relative lateral movement of the first and second retaining devices.

27. Regarding claims 11-14, 35-38, and 49-52, the clips made obvious by Darrey are spring clips. Without further structure, any point of reference or any structure that aids in alignment on the spring clips can be considered an alignment indicator including the curved channel defined by the clamping ends 10b.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 3/20/2007


GLENN K. DAWSON
PRIMARY EXAMER